FEB 2 3 2001

VORTRAN Medical Technology 1, Inc.

510(k) No: K003684

510(k) Summary

Submitter Information	VORTRAN Medical Technology 1, Inc. 3941 J Street, Suite 354, Sacramento, CA 95819
Contact Information	James Lee, Senior Vice President TEL: (800) 434-4034 FAX: (916) 454-0490
Trade Name	PercussiveNEB
~~Common Name~~	~~Ventilator, Non-Continuous~~
Device Class	Class II
Product code	73 BZD
Product classification	Per CFR Section 868.5905
Classification panel	Anesthesiology
Predicate device	1. PercussiveTech HF™ Model 2001 510(k) No: K981726 ~~VORTRAN Medical Technology 1, Inc. Sacramento, CA, USA~~ 2. Percussionaire IPV® (Intrapulmonary Percussionator) 510(k) No: K895485 / K905236 Percussionaire® Corporation, Bird Airlodge, Sandpoint, Idaho, USA 3. FLUTTER® Valve 510(k) No: K946083 Scandipharm, Birmingham, AL, USA
Device Description	The PercussiveNEB is an intrapulmonary percussive treatment device intended for the clearance of endobronchial secretions and operates with any 50 PSIG compressed gas source.
Intended Use	For use in the removal of mucus from the lungs of patients with retained endobronchial secretions.
Substantial Equivalency Evaluation	Laboratory testing was performed on the PercussiveNEB™ to demonstrate substantial equivalence to 3 different types of legally marketed mucus clearance devices: (1) the PercussiveTech HF™ (2) the Percussionaire® IPV® (Intrapulmonary Percussionator) and (3) the FLUTTER® Mucus Clearance Device.

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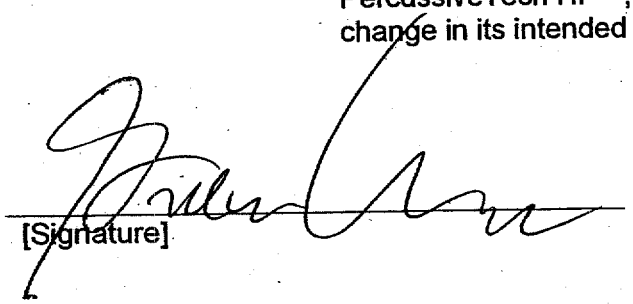
Operational Characteristics	The two key elements in measuring the performance of mucus clearance devices are: (1) the frequency and amplitude of patient's airway oscillation and (2) the quality and quantity of aerosol delivered if applicable. Testing protocols were established to measure these performance parameters per available guidelines.
Clinical Application	Moisture, intrapulmonary percussion, and the aerosol medication have been shown to thin and mobilize secretions. PercussiveNEB™ incorporates a nebulizer which delivers aerosolized medication while it cycles from 11 to 27 Hz with a typical pressure amplitude of 8 to 34 cm-H_2O. The PercussiveNEB is designed to oscillate during exhalation and inhalation to help increase the speed of gas along the walls of the bronchial airways.
Clinical Tests	None
Adverse S & E Information	None
Conclusion	The PercussiveNEB is substantially equivalent in operational characteristics and functionality to the predicate devices such as the PercussiveTech HF™, Percussionaire IPV® and Flutter®. There is no change in its intended use as cleared in the 510(k).



[Signature]

November 27, 2000

[Dated]

Gordon A. Wong, M.D.

[Typed Name]

President

[Title]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Gordon A. Wong, M.D.
Vortran Medical Technology 1, Inc.
3941 J St., Suite 354
Sacramento, CA 95819-3633

Re: K003684
Percussiveneb, Model PN-2001
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NHJ

Dear Dr. Wong:

This letter corrects our substantially equivalent letter of February 23, 2001, regarding the Percussiveneb, Model PN-2001. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NHJ as indicated above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003684

Device Name: PercussiveNEB™

Indication for Use:

For use in the removal of mucus from the lungs of patients with retained endobronchial secretions.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use : ✓ OR Over-the-Counter Use _____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

2/22/1

Division of Cardiovascular & Respiratory Devices
510(k) Number K003684